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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/938,667	08/27/2001	Jens Petersen	60117.000006	2505

7590

09/14/2005

Stanislaus Aksman
Hunton & Williams
Suite 1200
1900 K Street, N.W.
Washington, DC 20006

EXAMINER

FUBARA, BLESSING M

ART UNIT	PAPER NUMBER
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1618

DATE MAILED: 09/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/938,667

Applicant(s)

PETERSEN, JENS

Examiner

Blessing M. Fubara

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 June 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9-17, 29-38, 47, 49, 51-55, 57 and 62-64 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9-17, 29-38, 47, 49, 51-55, 57 and 62-64 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>6/22/05 & 7/26/05</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Examiner acknowledges receipt of supplemental IDS filed 06/22/05 and 07/26/05; request for continued examination under 37 CFR 1.114 filed 06/22/05 and amendment and remarks filed 12/14/04. Claims 9-17, 29-38, 47, 49, 51-55, 57 and 62-64 are pending.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 06/22/05 has been entered.

Claim Rejections - 35 USC § 103

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. Claims 9-17, 29-38, 47, 49, 51-55, 57 and 62-64 are rejected under 35 U.S.C. 103(a) as being unpatentable over RU 2 148 957 (English translation provided by applicants on Form PTO 1449) in view of Chen et al. (US 6,486,213).

RU 2 148 957 discloses a method of treating vesicoureteral reflux by injecting polyacrylamide hydrogel into the ostium ureteris of ureter (abstract; 4-6 full paragraphs on page 8). Claim 9 recites that the complex viscosity of the hydrogel is about 2 to 90 Pas and claim 15 states that the endoprosthesis (defined in the specification as a suspension in paragraph 25 and 36) is administered by injection. Thus, regarding the viscosity of the hydrogel, is noted that

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since the hydrogel of both the prior art and the instant claims are injected, it stands to reason that the hydrogel of the prior art has level of viscosity.

Chen discloses a hydrogel formulation that may be administered in form of a suspension (column 7, line 54; column 8, lines 4 and 5) and prepared from acrylamide and methylene-bis acrylamide (column 20, line 18); Chen discloses that the level of cross-linking in a hydrogel is estimated by reporting the ratio of the molarity of the crosslinker to the molarity of the monomer and suitable concentration of cross-linker in the polymerization reaction ranges from 0.005% to 1% with a preferred concentration range of 0.1% to 0.5% by weight (column 20, lines 31-45); and the suspending water is sterile (column 20, line 49; column 21, line 33), which implies pyrogen free medium.

Regarding claim 10, the person of ordinary skill in the art would know routine experimental procedure of using the amounts of methylene-bis-acrylamide required to produce the desired cross-linking in designated amount of the monomer unit, and in this case, acrylamide. Regarding claims 11, 12 and 29-34, the person of ordinary skill in the art would know routine experimental method of determining what percent of the total hydrogel is the polymer. Regarding claim 16, the person of ordinary skill in the relevant art would know the different positions at which to make the injections (ureter, urethra, colon, rectum).

RU 2 148 957 does not specifically disclose the reactants producing the acrylamide hydrogel. But as discussed above, Chen discloses the formation of acrylamide hydrogel from acrylamide and methylene-bis-acrylamide, which is the cross-linker. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare and inject acrylamide hydrogel into the ostium ureteris of ureter as disclosed by RU 2 148 957. One

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having ordinary skill in the art would have been motivated to prepare the acrylamide hydrogel from acrylamide and methylene-bis acrylamide in the appropriate ratios that would yield desired cross-linked hydrogel that would be expected to effectively treat vesicoureteral reflux.

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 9-15, 17, 29-38, 47 and 49 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 5, 7-12 and 44-50 of copending Application No. 09/938,670 (published as US 2002/0064512). Although the conflicting claims are not identical, they are not patentably distinct from each other because the polymeric compositions of both applications are the same and having monomeric units of less than 50 ppm does not distinguish the examined application over the co-pending application. The composition of the polymer is the same in both applications and the compositions can be used for treating cosmetic or functional defect as well as for treating incontinence. Claim 1 of the 09/938,670 contains the element of the instant claims that is implanted as an endoprosthesis to treat incontinence. The viscosity of 2-90 Pas is the same for the compositions of both applications. Co-pending claims 12 and 44 use the composition as implantable endoprosthesis

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or injectable endoprosthesis respectively. The instant claims administer the composition as an endoprosthesis or administer endoprosthesis that includes the composition. The copending composition, which is the same as the composition of the examined claims, will exhibit the same effect of treating incontinence when administered by implantation or injection of the endoprosthesis that contains the composition.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicant's argument regarding Vogel as disclosing particles that are not pliable has been carefully considered. The argument is not persuasive in the sense that applicants prepares the hydrogen, homogenizes the formed hydrogel and re-suspends the homogenate as suspension in pyrogen free water. The claims do not exclude particle form and secondly homogenization does not exclude particles as grinding the polyacrylamide formed from acrylamide and methylene-bis-acrylamide as does Vogel. However, this rejection is not made now in the current rejection.

Anticipation rejection by Pavlik (RU 2034465) and WO 96/04943 is not made.

Obviousness rejection over Vogel et al. (US 6,335,028) is not made.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Blessing Fubara
Patent Examiner
Tech. Center 1600

